DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

JUN 25 2004

Nancy Chapman, MPH, RD
President
Advocates for Better Children's Diets
1001 Connecticut Avenue, NW
Washington, DC 20036

Dear Ms. Chapman;

This is in response to your letter, dated April 30, 2004, to Dr. Robert E. Brackett concerning the beneficial effects of omega-3 fatty acids. You recommended that FDA favorably consider a FDAMA notification for nutrient content claims for DHA, EPA, and ALA omega-3 fatty acids. You noted that coronary heart disease (CHD) is our nation's leading killer and that the scientific evidence demonstrates that EPA and DHA, and to a lesser degree ALA, can reduce the risk of CHD. You also noted the beneficial effects of omega-3 fatty acids for all ages.

As you are aware, on January 16, 2004, FDA received a notification from Michael J. O'Flaherty of Olsson, Frank and Weeda, on behalf of Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc. The notification was submitted pursuant to section 403(r)(2)(G) of the Food, Drug, and Cosmetic Act (the act) for nutrient content claims for foods and dietary supplements containing DHA, EPA, and ALA.

Section 403(r)(2)(G) permits distributors and manufacturers to use claims if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences (NAS). These provisions are intended to expedite the process by which the scientific basis for such claims is established. Under section 403(r)(2)(G) of the act, any interested person may submit, at least 120 days before introducing the food with the labeled claim into interstate commerce, notifications for nutrient content claims based on authoritative statements that includes (1) the exact words to be used in the claim, (2) a concise description of the basis for the claim that was used to determine that the requirements for an authoritative statement have been satisfied, (3) a copy of the authoritative statement, and (4) a balanced representation of scientific literature relating to the nutrient level to which the claim refers.

The 120 day period passed on May 15, 2004, and the agency has filed the notification in a public docket (Docket No. 2004N-0217). Manufacturers may now lawfully label

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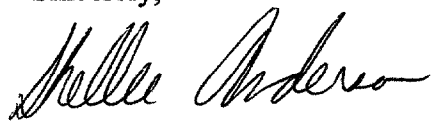
qualifying foods with the nutrient content claims detailed in the notification. However, because the agency disagrees with basis for the notified nutrient content claims for EPA and DHA, FDA intends to initiate rulemaking to itself define nutrient content claims for EPA and DHA.

Your letter notes that "DHA and EPA have been shown to be essential for the developing brain during pregnancy and the first two years of an infant's life" and urges FDA action based on scientific data documenting the important health benefits of DHA and EPA (long-chain n-3 fatty acids) for the developing fetus and young infant. While many infant formulas marketed in the United States contain DHA, use of fish oil containing a relatively high level of EPA was reported to slow growth and development of preterm infants (Ref. 1) and infant formulas currently marketed in the United States do not contain this fatty acid.

As your letter also notes, the effects of specific fatty acids (both preformed long-chain polyunsaturated fatty acids and their precursor fatty acids) differ from one another and their function may be specific for certain stages of growth and development. It is imperative to recognize the concomitant need for the long-chain n-6 fatty acids including arachidonic acid (ARA) and the critical importance of the ratio of n-6:n-3 fatty acids for infants. Impaired growth has been reported in studies of infants fed formulas containing n-3 long-chain fatty acids without ARA (Ref. 1-4) and raises concern over use of long-chain n-3 fatty acids without ARA in infant formulas. In that regard, the generally recognized as safe (GRAS) use of long-chain polyunsaturated fatty acids in infant formulas in the United States is the use of both DHA and ARA (n-3 and n-6 fatty acids, respectively) in specified amounts and ratios. See FDA's response letter to GRAS Notification 41 at http://www.cfsan.fda.gov (Ref. 5). Labels of infant formulas containing long-chain polyunsaturated fatty acids indicate that DHA and ARA are components of the products.

We hope this is helpful. If you have additional questions, do not hesitate to contact us.

Sincerely,



Shellee Anderson
Team Leader
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center of Food Safety
and Applied Nutrition

References

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3. Carlson, SE, Werkman, SH, Tolley, EA. 1996. Effect of long-chain n-3 fatty acid supplementation on visual acuity and growth of preterm infants with and without bronchopulmonary dysplasia. American Journal of Clinical Nutrition 63:687-697.
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